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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/734,692      | 12/11/2003  | Philip Stashenko     | 25669-003           | 4324             |

7590  
Mintz, Levin, Cohn, Ferris,  
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Boston, MA 02111

03/17/2008

EXAMINER

CHANDRA, GYAN

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/734,692

**Applicant(s)**

STASHENKO ET AL.

**Examiner**

GYAN CHANDRA

**Art Unit**

1646

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 26-29 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 26-29 and 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Applicant's response filed on 1/09/2008 is acknowledged and fully considered.

#### ***Status of Application, Amendments, And/Or Claims***

The amendments of claims 1, 26-29 and 31-33 and the cancellation of claim 2 and 30 have been made of record.

Claims 1, 26-29 and 31-33 are pending and under examination.

#### ***Response to Arguments***

##### ***Claim Objections/Rejections – withdrawn***

#### ***Claim Objections***

The objection of claim 1 is withdrawn in view of Applicants' amendment of claim 1 to include sequence identifier number for OC14 (i.e., SEQ ID NO: 50).

#### ***Claim Rejections - 35 USC § 102***

The rejection of claims 1, and 25-26 under 35 U.S.C. 102(e) as being anticipated by Choi, Y. (US Pub. No. 2003/0186297) is withdrawn in view of Applicants' amendments of claim 1 which now includes the limitation "wherein the activity of said gene is decreased by at least 10%".

#### ***Claim Rejections - maintained***

#### ***Claim Rejections - 35 USC § 112-written description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, and 26-33 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record on pages 3-7 of the previous Office Action mailed on 7/09/2007.

Applicants argue (page 5 of Response) that the instant invention is not limited to a specific compound and argue that the invention is drawn to a method of inhibiting osteoclast-mediated bone resorption by inhibiting OC14 gene. Applicants argue that the specification (pages 1-2 and 49) discloses methods for inhibiting osteoclast mediated bone resorption. Applicants provide a post filing art Battaglini et al (Bone, 42: 180-182, 2008) to support that SiRNA technology could be used to inhibit osteoclast differentiation and resorption activity.

Applicants' arguments have been fully considered but they are not persuasive because the specification does not disclose any compound selected from the group consisting of a fusion protein, a polypeptide, a peptidomimetic, an antisense polynucleotide, a prodrug, an antibody, a small molecule inhibitor or a ribozyme that inhibits OC14 gene activity and leads to inhibition of osteoclast-mediated bone resorption. The specification on pages 1-2 discloses, in general, how one of the skill in the art could use an antibody to inhibit a protein activity or use a compound to inhibit gene expression, but the specification does not disclose any compound selected from said group, which when administered to a subject or model inhibits said activity of OC14 of SEQ ID NO: 50 at least 10% and results in osteoclast-mediated bone resorption. Regarding applicants' arguments that the reference Battaglini et al teaches the SiRNA technology that can be used for inhibiting osteoclast-mediated bone resorption is

Art Unit: 1647

persuasive but the arguments are not relevant to the instant rejection because the specification at the time of filing does not disclose any compound selected from the group consisting of a fusion protein, a polypeptide, a peptidomimetic, an antisense polynucleotide, a prodrug, an antibody, a small molecule inhibitor or a ribozyme, which can inhibit the activity of OC14 at least 10% that results in reduction of osteoclast-mediated bone resorption. Therefore, the rejection is maintained.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra, Ph.D.  
Art Unit 1646  
29 February 2008  
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/Robert Landsman/  
Primary Examiner, Art Unit 1647